AMENDMENTS TO THE CLAIMS

A complete set of claims is included below, as well as the current status of each claim. This listing of claims replaces all prior versions, and listings, of claims in the application.

1. (original) A method for assessing and managing risks associated with utilizing a pharmaceutical product comprising:

identifying, characterizing and ranking adverse events caused by using the pharmaceutical product;

identifying a medication-use process associated with a pharmaceutical product;

identifying potential failure modes where the medication use process will not be adequate to protect patients from experiencing adverse side effects;

quantifying the potential effect of said failure mode to create a pharmaceutical hazard score, wherein said hazard score considers the severity and frequency of occurrence of the effects of said failure;

conducting a logical hazard assessment of said failure modes found to have a high hazard score to evaluate the need to mitigate the effect of said failure modes; and

designing a risk management intervention program to manage said adverse events.

2. (original) The method of claim 1 further comprising:

implementing said risk management program.

3. (original) The method of claim 2 further comprising:

measuring the effectiveness of said risk management program.

4. (original) The method of claim 3 wherein measuring the effectiveness of said risk management program comprises:

measuring and defining metrics, measurement systems, program goals, objectives and program performance analysis and reporting.

5. (currently amended) The method of claim 3 further comprising[[;]]:

integrating said effectiveness measurement into said pharmaceutical product hazard score.

6. (original) The method of claim 5 wherein the step of integrating said effectiveness measurement comprises:

reporting said effectiveness measurement.

7. (original) The method of claim 1 wherein the step of identifying, characterizing and ranking the adverse events caused by using the pharmaceutical product comprises:

analyzing available data from animal, toxicology, pharmacokinetic, pharmacodynamic and pharmacogenomic studies of the pharmaceutical product.

8. (original) The method of claim 1 wherein the step of identifying, characterizing and ranking the adverse events caused by using the pharmaceutical product comprises:

analyzing existing clinical safety data for the pharmaceutical product.

9. (original) The method of claim 1 wherein identifying, characterizing and ranking the adverse events caused by using the pharmaceutical product comprises:

analyzing risks identified in similar products.

10. (original) The method of claim 1 wherein the step of identifying, characterizing and ranking said failure modes comprises:

graphically depicting the medication use process of prescribing, dispensing, and administering the pharmaceutical product as a plurality of steps; and identifying subprocesses for each of said steps.

11. (original) The method of claim 1 wherein identifying potential failure modes of the medication use process comprises:

identifying one or more processes of prescribing, dispensing or administering the pharmaceutical product or a combination thereof, and optionally identifying subprocesses of said one or more processes.

12. (original) The method of claim 1, wherein said pharmaceutical hazard score comprises:

utilizing a pharmaceutical severity scale; and utilizing a pharmaceutical frequency of occurrence scale.

13. (original) The method of claim 1 wherein the logical hazard assessment comprises:

analyzing the criticality and detectability of the failure mode to determine the need to mitigate the failure mode.

14. (original) The method of claim 13 wherein the logical hazard assessment further comprises:

analyzing existing risk control measures for the failure mode to determine whether they are effective in mitigating the failure mode without further intervention.

15. (original) The method of claim 1 wherein the risk management intervention program comprises:

effective education, communications and/or control measures in redundant combinations and incorporating adult learning principles designed to be readily implemented in order to effectively reduce the incidence and consequences of said failure modes.

16. (original) The method of claim 1 wherein the risk management intervention program comprises:

a primary intervention targeted to reduce the incidence of each failure mode.

17. (original) The method of claim 1 wherein the risk management intervention program comprises:

one or more redundant backup interventions to decrease the occurrence of and/or mitigate the consequences of failure of the primary intervention.

18. (original) The method of claim 1 wherein the risk management intervention program comprises:

distributing interventions to multiple end users, wherein the multiple end users are selected from the group consisting of physicians, pharmacists, health care providers, caregivers and patients.

19. (original) The method of claim 1 wherein the risk management intervention program comprises:

coordinating care among multiple end users, wherein the multiple end users are selected from the group consisting of physicians, pharmacists, health care providers, caregivers and patients.

20. (original) The method of claim 1 wherein the risk management intervention program comprises:

tailoring said risk management intervention program to local medical practice standards and needs including, but not limited to the delegation of primary responsibility for the program from physician to support staff.

21. (original) The method of claim 1 wherein the risk management intervention program comprises:

designing interventions that are effective in transferring medical knowledge and reinforcing knowledge retention.

22. (original) The method of claim 1 wherein the risk management intervention program comprises:

utilizing one or more of adult learning principles, enablers, personal application, multiple media, repetitive messaging, self assessments, feedback, incentives and consequence messages.

23. (original) The method of claim 1 wherein the risk management intervention program comprises:

developing a risk communication curriculum to communicate risk to an end user, wherein the end user is selected from the group consisting of physicians, pharmacists, health care providers, caregivers and patients.

24. (original) The method of claim 1 wherein the risk management intervention program comprises:

transferring know-how, insights, techniques, methods, and processes from more experienced physicians and support staff to less experienced physicians and support staff.

25. (original) The method of claim 1 wherein the risk management intervention program comprises:

utilizing existing interventions and tools developed by one or more of clinicians, peer to peer forums, clinical consultations and preceptorships.

26. (original) The method of claim 1 wherein the risk management intervention program comprises:

implementing human behavior changing interventions.

27. (original) The method of claim 1 wherein the risk management intervention program comprises:

utilizing disease management approaches, principles, methods, techniques and tools to change end user behavior.

28. (original) The method of claim 1 wherein the risk management intervention program comprises:

integrating risk messages into promotional materials of the pharmaceutical product.

29. (original) The method of claim 1 wherein the risk management intervention program comprises:

utilizing a professional support network for the collection and management of data associated with the adverse events.

30. (original) The method of claim 29 wherein said data comprises:

occurrences of the adverse events.

31. (original) The method of claim 1 wherein the risk management program comprises:

educational resources for delivering information regarding prescribing, dispensing, and use of the pharmaceutical product.

32. (original) The method of claim 31 wherein the educational resources comprises:

identification of control measures for the pharmaceutical product.

33. (original) The method of claim 31 wherein the educational resources comprises:

classes to instruct and end user on said control measures.

34. (original) The method of claim 31 wherein said educational resources are available by electronic, written, audio, or video communication.

35. (original) The method of claim 1 wherein the risk management intervention program comprises:

implementing distribution controls wherein said distribution controls manage the availability of the pharmaceutical product.

36. (original) The method of claim 35 wherein the distribution controls comprise:

limiting availability of the pharmaceutical product to a single source.

37. (original) The method of claim 35 wherein the distribution controls comprise:

limiting availability of the pharmaceutical product to authorized pharmacies.

38. (original) The method of claim 35 wherein the distribution controls comprise:

requiring a pharmacist to be certified to dispense the pharmaceutical product.

39. (original) The method of claim 35 wherein the distribution controls comprise:

limiting physician prescribing rights.

40. (original) The method of claim 39 wherein limiting physician prescribing comprises:

limiting the number of refills per prescription, limiting the expiration date of a prescription, and/or limiting the form of a prescription.

41. (original) The method of claim 1 wherein the risk management intervention program comprises:

mandating periodic or intermittent tests for the existence of contraindications for the pharmaceutical product.

42. (original) The method of claim 41 wherein said contraindications comprise pregnancy.

43. (withdrawn) A method for creating educational materials for use in mitigating the risks of a pharmaceutical product comprising:

compiling a database of educational components wherein said components are useful in providing information regarding the risks of a pharmaceutical product or procedures to mitigate said risks;

selecting a plurality of said components from said database to create an educational tool kit wherein the components are selected based on the expected effectiveness of said component in managing the identified risks of the pharmaceutical product;

tailoring interventions to assure implementation by other end users;

designing a dissemination plan for distributing the educational materials to a target audience;

implementing the dissemination plan through forums and venues, such as learning labs, virtual learning forums, and preceptorships;

evaluating the expected impact of the educational tool kit on the target audience; and

adding, deleting, or modifying the selected components to achieve a desired expected impact.

44. (withdrawn) The method of claim 43 further comprising:

integrating a measurement of actual effectiveness of said components of said educational tool kit into said database.

45. (withdrawn) The method of claim 43 wherein said database is compiled from existing risk management programs.

46. (withdrawn) The method of claim 43 wherein the target audience comprises a patient being administered the pharmaceutical product.

47. (withdrawn) The method of claim 43 wherein the target audience comprises a patient's caregiver or family member.

48. (withdrawn) The method of claim 43 wherein the target audience comprises a physician prescribing the pharmaceutical product.

49. (withdrawn) The method of claim 43 wherein the target audience comprises a physician's clinical or office staff.

50. (withdrawn) The method of claim 43 wherein the target audience comprises a pharmacist dispensing the pharmaceutical product.

51. (original) A system comprising:

a logic configured to identify, characterize and rank adverse events caused by using a pharmaceutical product;

identify a medication use process associated with the pharmaceutical product;

identify potential failure modes of the medication use process;

quantify the potential effect of said failure modes to create a pharmaceutical hazard score, wherein said hazard score considers the severity and frequency of occurrence of the effects of said failure modes;

conduct a logical hazard assessment of said failure modes found to have a high hazard score to evaluate the need to mitigate the effect of said failure modes; and

design a risk management program to manage said adverse events.

52. (original) A system comprising:

a processor;

a memory operably connected to the processor, where the processor can access the memory;

a logic operably connected to the processor, where the logic is configured to:

identify, characterize and rank adverse events caused by using a pharmaceutical product;

identify a medication use process for the pharmaceutical product;

identify potential failure modes of the medication use process;

quantify the potential effect of said failure modes to create a pharmaceutical hazard score, wherein said hazard score considers the severity and frequency of occurrence of the effects of said failure modes;

conduct a logical hazard assessment of said failure modes found to have a high hazard score to evaluate the need to mitigate the effect of said failure modes; and

design a risk management program to manage said adverse events wherein said risk management program comprises control measures to reduce the incidence and consequences of said failure modes.

53. (original) A computer-readable medium storing processor executable instructions operable to perform a method, the method comprising:

identifying adverse events caused by using a pharmaceutical product;

identifying a medication use process for the pharmaceutical product;

identifying potential failure modes of the medication use process;

quantifying the potential effect of said failure modes to create a pharmaceutical hazard score, wherein said hazard score considers the severity and frequency of occurrence of the effects of said failure modes;

conducting a logical hazard assessment of said failure modes found to have a high hazard score to evaluate the need to mitigate the effect of said failure modes; and

designing a risk management program to manage said adverse events wherein said risk management program comprises control measures to reduce the incidence and consequences of said failure modes.

54. (original) A system comprising:

a means for identifying adverse events caused by using a pharmaceutical product;

a means for identifying a medication use process for the pharmaceutical product;

a means for identifying potential failure modes of the medication use process;

a means for quantifying the potential effect of said failure modes to create a pharmaceutical hazard score, wherein said hazard score considers the severity and frequency of occurrence of the effects of said failure modes;

a means for conducting a logical hazard assessment of said failure modes found to have a high hazard score to evaluate the need to mitigate the effect of said failure modes; and

a means for designing a risk management program to manage said adverse events wherein said risk management program comprises control measures to reduce the incidence and consequences of said failure modes.

a means for measuring, evaluating and reporting the effectiveness of a risk management program.

55. (withdrawn) A pharmaceutical product risk assessment and management kit comprising: one or more intervention components, wherein said one or more intervention components are selected for inclusion in said pharmaceutical product risk assessment and management kit by a pharmaceutical product risk assessment and management method.

56. (withdrawn) A pharmaceutical product risk assessment and management kit of claim 55, wherein said kit is selected from the group consisting of a patient kit, a physician kit and a pharmacist kit.

57. (withdrawn) A pharmaceutical product hazard scoring chart comprising: a first column of a pharmaceutical severity scale; and a second column of a pharmaceutical frequency of occurrence scale; wherein a pharmaceutical hazard score is the product of said first column and said second column.